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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MCKELVEY, TERRY ALAN

ART UNIT	PAPER NUMBER
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1636

12

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,855

Applicant(s)

RASMUSSEN, MICHAEL
DOLBERG

Examiner

Terry A. McKelvey

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/30/02, 1/30/03.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,7-20,22,23,32,44,45,59 and 61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,2,4,5,7-20,22,23,32,44,45,59 and 61 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

Art Unit: 1636

DETAILED ACTION

The applicant's response to the restriction requirement, including the requirement to indicate which claims are readable on the elected invention, filed 10/30/02 and 1/30/03, is noted. In response, the following is noted.

First, with regard to the acknowledgement of the receipt of priority document, indicated as not being received in Paper No.7, filed 10/2/02, this was checked off in error by the patent analyst who filled out the forms attached to the communication.

Second, the applicant indicates that claims 1, 2, 4, 5, 7-20, 22, 23, 32, 44, 45, 59, and 61 read on the elected species, but this is clearly not correct because claim 10 is drawn to "wherein the precursor can be degraded to produce free galactose". Because galactose is the elected precursor, it cannot be degraded so as to produce galactose, and thus this claim is not readable on the elected species. Claim 11 is drawn to non-galactose precursors, and claims 12-14 also appear to be drawn to non-elected species.

Third, the applicant argues that the election of species requirements do not comply with the unity of invention standard under the Patent Cooperation Treaty and thus is improper. This argument is completely not persuasive because Markush groups or

Art Unit: 1636

alternatives are also governed by PCT Rule 13.2. When dealing with alternatives, if it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered by the examiner. See MPEP 1850, Section D. "Markush Practice". As shown below, the cited reference teaches the claimed amplification unit comprising the gene for galE (galactose epimerase), drawn to the elected species, and even teaches a method for constructing a host cell comprising at least one copy of an amplification unit. There is no unity of invention because there is no shared same or corresponding technical feature that is a contribution over the prior art. Therefore, the lack of unity/election of species requirement set forth in Paper No. 7, mailed 10/2/02 is proper and remains of record.

Fourth, due to reconsideration of the lack of unity requirement, it was determined that the following election requirement is proper, which is in addition to the previous election of species. The examiner apologizes for not setting forth the election requirement earlier.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

Art Unit: 1636

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 4, 5, 7-20, 22, and 23, drawn to method for increasing the number of copies of an amplification unit and method for constructing a host cell comprising at least one copy of an amplification unit.

Group II, claim(s) 32, 44, 45, 59, and 61, drawn to amplification unit, nucleic acid, host cell, and process for producing a polypeptide of interest.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

PCT Rule 13.2 requires that unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-II do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The "special technical feature" of Group II is an amplification unit comprising an expression cassette comprising at least one copy of a gene of interest and an expressible copy of a conditionally essential chromosomal gene of a host cell, which is shown by U.S. Patent No. 5,435,730 to lack novelty or inventive step for the reasons cited in the corresponding PCT International Preliminary Examination Report of record. U.S. Patent No. 5,435,730 discloses recombinant DNA molecules comprising the *Streptomyces gal* operon (which includes the *galE*, *galT*, *galK* genes and their promoter) or parts of it, which anticipates the claimed amplification unit. This reference further teaches the use of the *gal* operon as a selection marker in a host mutant which contains a nonfunctional *gal* operon: a recombinant DNA molecule comprising the *gal* operon and a gene of

Art Unit: 1636

interest can be transformed into a host cell and integrated by homologous recombination. This method allows the expression of a gene of interest without the need of an antibiotic selection (abstract; columns 6-7). Groups I-II do not share the same or corresponding technical feature and thus lack unity.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Conclusion

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014.

NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.


Any inquiry concerning rejections or other major issues in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (703) 305-7213. The examiner can normally be reached on

Art Unit: 1636

Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

April 7, 2003